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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,819	11/06/2000	Akira Aomatsu	5774-01-MJA	5038

7590 02/06/2002  
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EXAMINER

JARVIS, WILLIAM R A

ART UNIT PAPER NUMBER

1614

DATE MAILED: 02/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/674,819

Applicant(s)

AOMATSU, AKIRA

Examiner

William R. Jarvis

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. Applicant's election with traverse of gabapentin and propylene glycol in Paper No. 7 is acknowledged. The traversal is on the ground(s) that all the compounds share the same general formula. This is found persuasive and all species will be examined as a single general inventive concept under PCT Rule 13.1 as requested by applicant. However, applicant should note that since the species are all considered of the same inventive concept, a reference teaching one specie makes the other species obvious to one skilled in the art.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite since no process steps are present. Claim 12 merely states: A process for the preparation of a solid composition containing....with a humectant for manufacturing a pharmaceutical composition. At least one step of combining the components of the composition is required. In addition, it is suggested that the steps be numbered in order so that they are more easy to read.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's submitted references U.S. Patents 5,025,035 (Wallace) or 5,084,479 (Woodruff), European Patent 458,751, or the patent abstract of Japanese Patent 63253022. Wallace and Woodruff disclose pharmaceutical compositions of gabapentin and other 4-amino-3-substituted-butanoic acid derivatives with applicant's preferred humectants propylene glycol, glycerin, and sorbitol; see col. 2, lines 13-57 of Wallace and col. 3, line 35 to col. 4, line 12 of Woodruff in particular. European Patent 458,751 disclose compositions of gabapentin and related compounds with excipients including sorbitol, monoglycerides, diglycerides, and triglycerides; see page 4, line 55

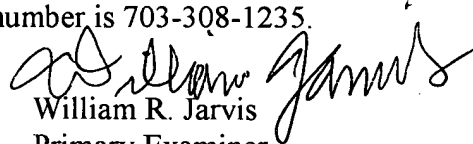
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to page 5, line 51. The Japanese patent abstract discloses compositions of applicant's preferred compound baclofen with propylene glycol as an excipient. Some claims differ in that they require humectants such as ethylene and butylene glycol which are not taught by the prior art. However, since these are conventional humectants in the pharmaceutical arts, it would have been obvious to one skilled in the art to employ them in the claimed compositions. The claimed amounts are obvious since it is within the skill of the pharmaceutical artisan to determine the amount of drug that provides the therapeutic effect most effective for treating the patient's condition while minimizing adverse side effects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. Jarvis whose telephone number is 703-308-4613. The examiner can normally be reached on Monday, Tuesday, Thursday & Friday 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
William R. Jarvis  
Primary Examiner  
Art Unit 1614

wrj  
February 6, 2002